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PATENT

CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

PIZZA et al.

Serial No.: 10/611,398

Filing Date: June 30, 2003

Title: IMMUNOGENIC DETOXIFIED MUTANTS
OF CHOLERA TOXIN

Examiner: Not Assigned

Group Art Unit: 1642

Confirmation No.: 1890

Customer No.: 27476

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

Enclosed is an Information Disclosure Statement and accompanying Form
PTO/SB/08A for the above-identified patent application.


- ☒ In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required.
- ☐ In accordance with 37 C.F.R. §1.97(c), also enclosed is:
- ☐ the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
 - ☐ a statement as specified in 37 C.F.R. §1.97(e).
- ☐ In accordance with 37 C.F.R. §1.97(d), a statement as specified in 37 C.F.R. § 1.97(e) and the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) are also enclosed.

- ☐ Check No. ____ in the amount of \$____ for the total fee is attached.
- ☒ A return receipt postcard is also enclosed.
- ☐ Please charge \$_____ to Deposit Account No. 18-1648 for the total fee.
This paper is being submitted in duplicate.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: August 9, 2005

By: 
Dahna S. Pasternak
Registration No. 41,411

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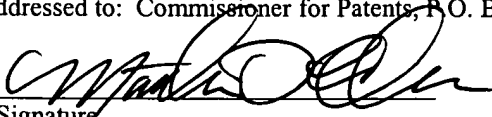
USSN: 10/611,398
Dkt. No.: 2300-0338.02
PP000338.0105

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Examiner: Not Assigned

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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.
§§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, copies of the Foreign Patent Documents and Non Patent Literature Documents cited in the attached Form PTO/SB/08 are enclosed.
- ☒ No copy of the U.S. publication A1 listed on the attached Form PTO/SB/08A are being provided because the Office waives the requirement under 37 C.F.R. 1.98 (a) (2) (i) for submitting a copy of each cited U.S. patent and each U. S. patent application publication for all U.S. national patent applications filed after June 30, 2003

- ☐ No copies of the publications listed on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. _____ to which the above-identified application claims priority under 35 U.S.C. §120.
- ☐ Publication(s) _____ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to PCT application serial no. _____ and mailed on _____.
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____. English language publication ____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) ____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) ____ cited in the attached Form PTO/SB/08A.
- ☐ Enclosed is a copy of pending patent Application Serial No. _____.

This Information Disclosure Statement is filed within any one of the following time periods:

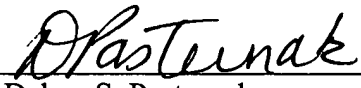
- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

Respectfully submitted,

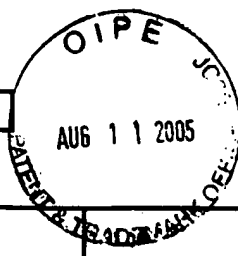
Date: August 9, 2005

By: 
Dahna S. Pasternak
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PTO/SB/08A (08-00)

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet 1		of 3		Application Number 10/611,398 (Confirmation No. 1890)	
				Filing Date June 30, 2003	
				First Named Inventor PIZZA et al.	
				Group Art Unit 1642	
				Examiner Name Unassigned	
				Attorney Docket Number PP000338.0105 (2300-0338.02)	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A1	5,182,109		Tamura, et al.	01-26-1993

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
	B1	WO	95/09649		MEDEVA HOLDINGS B.V.	04-13-1995	
	B2	WO	95/34323		CONNAUGHT LABORATORIES LIMITED	12-21-1995	
	B3	WO	96/06627		THE ADMINISTRATORS OF THE TULANE EDUCATIONAL FUND	03-07-1996	
	B4	WO	99/58145		UNIVERSITY OF BRISTOL	11-18-1999	
	B5	WO	00/18434		AMERICAN CYNAMID COMPANY	04-06-2000	
	B6	EP	0396964		SCLAVO S.P.A.	11-14-1990	
	B7	EP	0462534		SCLAVO S.P.A.	12-27-1991	
	B8	GB	9320454.3		MEDEVA HOLDINGS B.V.		
	B9	GB	9324743.5		MEDEVA HOLDINGS B.V.		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number.

² See attached Kinds of U.S. Patent Documents.

³ Unique citation designation number.

⁴ See attached Kinds of U.S. Patent Documents.

⁵ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁶ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁷ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

⁸ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08A (08-00)

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/611,398 (Confirmation No. 1890)
				Filing Date	June 30, 2003
				First Named Inventor	PIZZA et al.
				Group Art Unit	1642
				Examiner Name	Unassigned
Sheet	2	of	3	Attorney Docket Number	PP00338.105 (2300-0338.02)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C1	Burnette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)
	C2	Burnette, <i>Vaccine Research & Developments</i> Marcel Dekker Inc., New York, New York (1992)
	C3	Clements, et al., "Adjuvant Activity of Escherichia Coli Heat-Labile Enterotoxin and Effect on the Induction of Oral Tolerance in Mice to Unrelated Protein Antigens." <i>Vaccine</i> 6:269-277 (1988)
	C4	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)
	C5	de Haan, et al., "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)
	C6	Del Guidice, et al., "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)
	C7	Douce, et al., "Mutants of Escherichia Coli Heat-Labile Toxin Lacking ADP-Ribosyltransferase Activity act as Nontoxic, Mucosal Adjuvants." <i>PNAS USA</i> 92:1644-1648 (1995)
	C8	Douce, et al., "Intranasal Immunogenicity and Adjuvanticity of Site Directed Mutant Derivatives of Cholera Toxin." <i>Infect. Immun.</i> 65:2821-2828 (1997)
	C9	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)
	C10	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)
	C11	Green, Bruce, Curriculum Vitae
	C12	Hagen, Michael, Curriculum Vitae
	C13	Hagiwar, et al., Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)
	C14	Hartman, et al., "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed Shigella Vaccines." <i>Infect. Immun.</i> 67:5841-5847 (1999)
	C15	Hazama, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by using a Recombinant Glycoprotein D Fused with Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2." <i>Immunology</i> 78:643-649 (1993)
	C16	Hirst, et al., "Cholera Toxin and Related Enterotoxins as Potent Immune Modulators." <i>J. Appl. Microb. Symp. Suppl.</i> 48:26S-34S (1998)
	C17	Hirst, <i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , Chapter 6, Academic Press, pgs. 104-130, (1999)
	C18	Holmgren, et al., "Cholera Toxin and Cholera B Subunit as Oral-Mucosal Adjuvant and Antigen Vector Systems." <i>Vaccine</i> 11:1179-1184 (1993)
	C19	Lycke, et al., "Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens." <i>Immunol.</i> 56:301-308 (1986)
	C20	Lycke, et al., "The Mechanism of Cholera Toxin Adjuvanticity." <i>Res. Immunol.</i> 198:504-520 (1997)
	C21	Martindale, <i>Royal Pharmaceutical Society of Britain</i> Pharmaceutical Press, London, England, pgs.1277-1304(1993)
	C22	Rappouli, et al., "Structure and Mucosal Adjuvanticity of Cholera and Escherichia Coli Heat-Labile Enterotoxins." <i>Immunol. Today</i> 20:493-500 (1999)
	C23	Spangler, "Structure and Function of Cholera Toxin and The Related Escherichia Coli Heat-Labile Enterotoxin." <i>Microbiol. Rev.</i> 56:622-647 (1992)
	C24	Streatfield, et al., "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from Escherichia Coli Promote Holotoxin Assembly and Stability In Vivo." <i>PNAS USA</i> 89:12140-12144 (1992)
	C25	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 nd Ed., Academic Press, pgs. 696-697
	C26	Tsuji, et al., "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic Escherichia Coli Enterotoxin and its Strong Adjuvant Action." <i>Immunology</i> 90:176-182 (1997)

Examiner Signature		Date Considered	
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